IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. CIPLA LIMITED and CIPLA USA, INC., Defendants.	)	C.A. No.: ____

COMPLAINT

Novartis Pharmaceuticals Corporation ("NPC") and Novartis AG (collectively "Novartis"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Cipla Limited and Cipla USA, Inc. (collectively, "Cipla" or "Defendants"). This action relates to Abbreviated New Drug Application ("ANDA") No. 218228 (the "Cipla ANDA") filed by Defendants with the United States Food and Drug Administration ("FDA"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of siponimod tablets (0.25 mg, 1 mg, and 2 mg), generic versions of Novartis's MAYZENT® (siponimod) tablets[1] (collectively, the "ANDA Product"), prior to the expiration of U.S. Patent Nos. 8,492,441 ("the '441 patent"), 11,944,602 ("the '602 patent"), and 12,071,402 ("the '402 patent) (collectively, "the Asserted Patents").

[1] Novartis's MAYZENT® (siponimod) tablets are referred to as EQ 0.25 mg base, EQ 1 mg base, and EQ 2 mg base in the FDA's official publication of approved drugs (the "Orange Book"). For purposes of this complaint, Novartis will assume that Cipla considers these dosages to be equivalent and will adopt Cipla's nomenclature.

PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Novartis AG is a company organized and existing under the laws of Switzerland, having a principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

B. Cipla Limited and Cipla USA, Inc.

4. Upon information and belief, Defendant Cipla Limited is a corporation organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

5. Upon information and belief, Defendant Cipla USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Independence Blvd., Suite 300, Warren, New Jersey 07059. Upon information and belief, Cipla USA, Inc. is an indirect, wholly owned subsidiary of Cipla Limited. *See, e.g.*, *Acerta Pharma B.V. et al. v. Cipla Limited and Cipla USA, Inc.*, 24-587-GBW (D. Del.) (D.I. 10 at 3).

6. Upon information and belief, the Cipla Defendants are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products within the United States. Upon information and belief, the acts of the Cipla Defendants complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

7. Upon information and belief, Cipla is a generic pharmaceutical organization that works to develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

DEFENDANTS' INFRINGING ACTS

8. In letter dated May 18, 2023 (the "First Cipla Notice Letter"), Defendants notified Novartis (i) that Cipla Limited submitted to the FDA ANDA No. 218228, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of siponimod tablets (0.25 mg, 1 mg, and 2 mg) in or into the United States, including Delaware, prior to the expiration of the '441 patent and (ii) that ANDA No. 218228 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '441 patent.

9. In a letter dated December 30, 2024 (the "Second Cipla Notice Letter"), Defendants notified Novartis (i) that Cipla Limited submitted to the FDA ANDA No. 218228, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of siponimod tablets (0.25 mg, 1 mg, and 2 mg) in or into the United States, including Delaware, prior to the expiration of the '602 and '402 patents and (ii) that ANDA No. 218228 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '602 and '402 patents. The Second Cipla Notice Letter further stated that this certification is cumulative and does not change Cipla's earlier certification against the '441 patent.

10. Defendants have committed an act of infringement in this judicial district by filing the Cipla ANDA with the intent to make, use, sell, offer for sale, and/or import the ANDA Product in or into this judicial district prior to the expiration of the Asserted Patents, an act of infringement that has led and will lead to foreseeable harm and injury to NPC, a Delaware corporation.

11. Upon information and belief, Cipla Limited acted in concert with and/or directed Cipla USA, Inc. in the preparation and submission of the Cipla ANDA and, if the Cipla ANDA is approved, will act in concert with and direct Cipla USA, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product in or into the United States, including Delaware, prior to the expiration of the Asserted Patents.

12. Upon information and belief, Cipla Limited has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Cipla USA, Inc.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

13. Upon information and belief, Cipla USA, Inc. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Cipla Limited; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

14. Cipla Limited has availed itself of the legal protections of the State of Delaware by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court of the District of Delaware. *See, e.g.*, *Acerta Pharma B.V. et al. v. Cipla Limited et al.*, C.A. No. 24-587-GBW; *Gilead Scis., Inc. v. Cipla Limited*, C.A. No. 23-1480-MN; *Hikma Pharms. USA, Inc. v. Cipla USA, Inc. and Cipla Limited*, C.A. No. 23-1157-GBW.

15. Cipla USA, Inc. has availed itself of the legal protections of the State of Delaware by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court of the District of Delaware. *See, e.g.*, *Acerta Pharma B.V. et al. v. Cipla Limited et al.*, C.A. No. 24-587-GBW; *Hikma Pharms. USA, Inc. v. Cipla USA, Inc. and Cipla Limited*, C.A. No. 23-1157-GBW.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Cipla Limited under Federal Rule of Civil Procedure 4(k)(2) because, upon information and belief, Cipla Limited is organized under the laws of India and the exercise of personal jurisdiction over Cipla Limited in any judicial district is consistent with the United States Constitution and laws.

18. This Court has personal jurisdiction over Cipla USA, Inc. because Cipla USA, Inc. is a corporation organized and existing under Delaware law.

19. This Court also has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, upon information and belief, Defendants have committed or aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting the Cipla ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts will lead to foreseeable harm and injury to NPC, a Delaware corporation.

20. Upon information and belief, the effort to seek approval for the Cipla ANDA and to manufacture, import, market, and/or sell Defendants' ANDA Product upon approval has been a cooperative and joint enterprise and venture between Cipla Limited and Cipla USA, Inc.

21. This Court also has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, upon information and belief, Defendants will, upon approval of the Cipla ANDA, market, distribute, offer for sale, and/or sell Defendants' ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in the State of Delaware.

22. This Court also has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, upon information and belief, Defendants' ANDA Product, upon approval of the Cipla

ANDA, will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

23. This Court also has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, upon information and belief, Defendants' affiliations with the State of Delaware, including Cipla USA, Inc.'s organization or incorporation in Delaware, Cipla Limited and Cipla USA, Inc.'s availing themselves of the legal protections of the State of Delaware, and Cipla Limited's ownership of and actions in concert with Cipla USA, Inc. are sufficiently continuous and systematic as to render Defendants at home in this forum.

24. Upon information and belief, Cipla Limited and Cipla USA, Inc. operate as an integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA Product, throughout the United States including in this judicial district.

25. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc.

26. Venue is proper in this Court because Cipla USA, Inc. is organized under the laws of the State of Delaware and therefore resides in this judicial district, and Cipla Limited is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. §§ 1391(c)(3), 1400(b). Defendants have also previously conceded that venue is proper in Delaware for at least the cases listed above and have conceded that venue is proper in Delaware for purposes of the counterclaims filed in those cases.

THE PATENTS-IN-SUIT AND MAYZENT®

27. NPC is the owner of the ’441 patent, titled “Dosage Regimen of an S1P Receptor Agonist.” The ’441 patent was duly and legally issued on July 23, 2013. A true and correct copy of the ’441 patent is attached hereto as Exhibit A. The ’441 patent expires on November 30, 2030, excluding any pediatric exclusivity.

28. Novartis AG is the owner of the ’602 patent, titled “Treatment of Autoimmune Disease in a Patient Receiving Additionally a Beta-Blocker.” The ’602 patent was duly and legally issued on April 2, 2024. A true and correct copy of the ’602 patent is attached hereto as Exhibit B. The ’602 patent expires on July 24, 2036, excluding any pediatric exclusivity.

29. Novartis AG is the owner of the ’402 patent, titled “Immunosuppressant Formulations.” The ’402 patent was duly and legally issued on August 27, 2024. A true and correct copy of the ’402 patent is attached hereto as Exhibit C. The ’402 patent expires on January 5, 2032, excluding any pediatric exclusivity.

30. NPC is the holder of New Drug Application (“NDA”) No. 209884 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of MAYZENT® (siponimod) tablets. MAYZENT® is currently indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

31. One or more claims of each of the Asserted Patents cover MAYZENT® and/or its use.

32. The FDA’s official publication of approved drugs (the “Orange Book”) lists the Asserted Patents in connection with MAYZENT®.

INFRINGEMENT OF THE ASSERTED PATENTS

FIRST COUNT FOR PATENT INFRINGEMENT (’441 PATENT)

33. Novartis realleges, and incorporates in full herein, each preceding paragraph.

34. Novartis received the First Cipla Notice Letter dated May 18, 2023, purporting to include a Notice of Certification for ANDA No. 218228 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’441 patent.

35. The ’441 patent claims, *inter alia*, a method of administering to a subject in need thereof a medication comprising a S1P receptor agonist, whereby said S1P receptor modulator or agonist is given at a dosage lower than the standard daily dosage of said S1P receptor modulator or agonist during the initial period of treatment and then the dosage is increased, up to the standard daily dosage of said S1P receptor agonist.

36. At least one claim, including claim 1, of the ’441 patent covers FDA-approved methods of administering MAYZENT®.

37. Upon information and belief, Defendants submitted ANDA No. 218228 to the FDA, under Section 505(j) of the Act, and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic siponimod tablets containing 0.25 mg, 1 mg, and 2 mg siponimod in or into the United States, including Delaware. Upon information and belief, if the FDA approves ANDA No. 218228, physicians, health care providers, and/or patients will use Defendants’ generic siponimod tablets according to Defendants’ provided instructions and/or label and will directly infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1, of the ’441 patent.

38. Upon information and belief, if the FDA approves ANDA No. 218228, Defendants know and intend that physicians, health care providers, and/or patients will prescribe, administer, and/or use Defendants’ generic siponimod tablets according to Defendants’ provided instructions

and/or label in an infringing manner, and will therefore induce infringement of at least one claim, including claim 1, of the ’441 patent with the requisite intent under 35 U.S.C. § 271(b).

39. Upon information and belief, if the FDA approves ANDA No. 218228, Defendants will sell or offer to sell their generic siponimod tablets with provided instructions and/or label in an infringing manner, wherein Defendants’ generic siponimod tablets are a material part of the claimed invention, wherein Defendants know that physicians will prescribe, health care providers will administer, and/or patients will use Defendants’ generic siponimod tablets in accordance with Defendants’ provided instructions and/or label, wherein such use will directly infringe at least one claim, including claim 1, of the ’441 patent, and wherein generic siponimod tablets are not staple articles or commodities of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants will thus contribute to the infringement of at least one claim, including claim 1, of the ’441 patent under 35 U.S.C. § 271(c).

40. Novartis received the First Cipla Notice Letter dated May 18, 2023, purporting to include a Notice of Certification for ANDA No. 218228 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’441 patent. The First Cipla Notice Letter did not allege non-infringement as to at least claim 1 of the ’441 patent.

41. Upon information and belief, Defendants had actual knowledge of the ’441 patent prior to the submission of ANDA No. 218228 to the FDA.

42. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 218228 complained of herein were done by and for the benefit of Defendants.

43. If Defendants’ marketing and sale of generic siponimod tablets prior to expiration of the ’441 patent and all other relevant activities are not enjoined, Novartis will suffer substantial and irreparable harm for which there is no adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT ('602 PATENT)

44. Novartis realleges, and incorporates in full herein, each preceding paragraph.

45. Novartis received the Second Cipla Notice Letter dated December 30, 2024, purporting to include a Notice of Certification for ANDA No. 218228 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '602 patent.

46. The '602 patent claims, *inter alia*, a method of treating an autoimmune disease in a patient comprising a) administering to said patient an initial titration regimen of siponimod; b) administering to said patient 1-15 mg siponimod daily as a maintenance regimen; and c) introducing in said patient a beta-blocker treatment the earliest at the first day when said patient is receiving the dosage of the maintenance regimen; wherein said initial titration regimen comprises administering siponimod at a dosage lower than the dosage of the maintenance regimen and then increasing the dosage stepwise up to the dosage of the maintenance regimen.

47. At least one claim, including claim 1, of the '602 patent covers FDA-approved methods of treatment using MAYZENT®.

48. Upon information and belief, Defendants submitted ANDA No. 218228 to the FDA, under Section 505(j) of the Act, and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic siponimod tablets containing 0.25 mg, 1 mg, and 2 mg siponimod in or into the United States, including Delaware. Upon information and belief, if the FDA approves ANDA No. 218228, physicians, health care providers, and/or patients will use Defendants' generic siponimod tablets according to Defendants' provided instructions and/or label and will directly infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1, of the '602 patent.

49. Upon information and belief, if the FDA approves ANDA No. 218228, Defendants know and intend that physicians, health care providers, and/or patients will prescribe, administer,

and/or use Defendants' generic siponimod tablets according to Defendants' provided instructions and/or label in an infringing manner, and will therefore induce infringement of at least one claim, including claim 1, of the '602 patent with the requisite intent under 35 U.S.C. § 271(b).

50. Upon information and belief, if the FDA approves ANDA No. 218228, Defendants will sell or offer to sell their generic siponimod tablets with provided instructions and/or label in an infringing manner, wherein Defendants' generic siponimod tablets are a material part of the claimed invention, wherein Defendants know that physicians will prescribe, health care providers will administer, and/or patients will use Defendants' generic siponimod tablets in accordance with Defendants' provided instructions and/or label, wherein such use will directly infringe at least one claim, including claim 1, of the '602 patent, and wherein generic siponimod tablets are not staple articles or commodities of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants will thus contribute to the infringement of at least one claim, including claim 1, of the '602 patent under 35 U.S.C. § 271(c).

51. Novartis received the Second Cipla Notice Letter dated December 30, 2024, purporting to include a Notice of Certification for ANDA No. 218228 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '602 patent. The Second Cipla Notice Letter did not allege non-infringement as to at least claim 1 of the '602 patent.

52. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 218228 complained of herein were done by and for the benefit of Defendants.

53. If Defendants' marketing and sale of generic siponimod tablets prior to expiration of the '602 patent and all other relevant activities are not enjoined, Novartis will suffer substantial and irreparable harm for which there is no adequate remedy at law.

54. This action was commenced within 45 days of Novartis's receipt of the Second Cipla Notice Letter.

THIRD COUNT FOR PATENT INFRINGEMENT ('402 PATENT)

55. Novartis realleges, and incorporates in full herein, each preceding paragraph.

56. Novartis received the Second Cipla Notice Letter dated December 30, 2024, purporting to include a Notice of Certification for ANDA No. 218228 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '402 patent.

57. The '402 patent claims, *inter alia*, a solid phase pharmaceutical composition comprising one or more pharmaceutically acceptable non-basic excipients and 1-{4-[1-(4-cyclohexyl-3-trifluoromethyl-benzyloxyimino)-ethyl]-2-ethyl-benzyl}-azetidine-3-carboxylic acid or a pharmacologically acceptable salt thereof, wherein at least one of the one or more pharmaceutically acceptable non-basic excipients is glyceryl behenate, and wherein the solid phase pharmaceutical composition does not comprise magnesium stearate.

58. At least one claim, including claim 1, of the '402 patent covers MAYZENT®.

59. Upon information and belief, Defendants submitted ANDA No. 218228 to the FDA, under Section 505(j) of the Act, and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic siponimod tablets containing 0.25 mg, 1 mg, and 2 mg siponimod in or into the United States, including Delaware.

60. Upon information and belief, if the FDA approves ANDA No. 218228, Defendants generic siponimod tablets will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '402 patent under 35 U.S.C. § 271(a).

61. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including claim 1, of the '402 patent by submitting, or causing to be

submitted, to the FDA, ANDA No. 218228 seeking approval to manufacture, use, import, offer to sell or sell Defendants' ANDA Product before the expiration date of the '402 patent. Upon information and belief, the products described in ANDA No. 218228 would infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '402 patent under 35 U.S.C. § 271(e)(2)(A).

62. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 218228 complained of herein were done by and for the benefit of Defendants.

63. If Defendants' marketing and sale of generic siponimod tablets prior to expiration of the '402 patent and all other relevant activities are not enjoined, Novartis will suffer substantial and irreparable harm for which there is no adequate remedy at law.

64. This action was commenced within 45 days of Novartis's receipt of the Second Cipla Notice Letter.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

65. Judgment that Defendants Cipla Limited and Cipla USA, Inc. have infringed one or more claims of the Asserted Patents by filing ANDA No. 218228;

66. A permanent injunction restraining and enjoining Defendants, and their affiliates, subsidiaries, and each of their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the ANDA Product until the expiration of the Asserted Patents, inclusive of any extensions and additional periods of exclusivity;

67. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 218228 shall be a date that is not earlier than the latest to expire of the '441, '602, and '402 patents, inclusive of any extensions and additional periods of exclusivity;

68. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the Asserted Patents;

69. Damages or other monetary relief from Defendants for the infringement, inducement of infringement, and/or contributory infringement of the Asserted Patents if one or both of the Defendants engage in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the ANDA Product prior to the latest expiration date of the '441, '602, and '402 patents, inclusive of any extensions and additional periods of exclusivity;

70. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

71. Novartis's costs and expenses in this action; and

72. Such other and further relief as the Court may deem just and proper.

Dated: February 14, 2025

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